DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Philips Ultrasound, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

November 5, 2015

Re: K110414
Trade/Device Name: QLAB 8.1 Quantification Software with additional EA Plug-in
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communication system
Regulatory Class: II
Product Code: LLZ
Dated: June 3, 2011
Received: June 6, 2011

Dear Mr. Job:

This letter corrects our substantially equivalent letter of June 21, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of *In Vitro* Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K110414

Device Name: QLAB 8.1 Quantification Software with additional EA plug-in.

Indications for Use:

QLAB Quantification Software is a software application package. It is designed to view and quantify image data acquired on Philips Medical Systems ultrasound products.

Prescription Use X AND/OR **Over-the-counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110414

5. 510(k) Summary

This summary of safety and effectiveness is provided as part of the Premarket Notification in compliance with 21CFR. Part 807, Subpart E, Section 807.92

1) Submitter's name, address, telephone number, contact person

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Date prepared: April 18, 2011

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name:	Picture Archiving and Communications Systems Workstation
Proprietary Name:	QLAB Quantification Software 8.1
Classification Name:	CFR 892.2050, system, image processing, radiological, Product code LLZ, Class II

3) Substantially Equivalent Devices

Philips Ultrasound believes that the QLAB 8.1 software with the EA plug-in is substantially equivalent to other commercially available products, specifically the Size Compare feature cleared on the Philips iU22 Ultrasound System in K093563.

4) Device Description

QLAB 8.1 is a software application that is available either as a stand-alone product that can function on a standard PC, a dedicated workstation, and on-board Philips' ultrasound systems. It can be used for the on-line and off-line review and quantification of ultrasound studies.

QLAB 8.1 introduces a new plug-in into the stand-alone version of the product: Elastography Analysis (EA).

Elastography Analysis (EA) displays 2D images and elastograms acquired with the elastography imaging mode feature on an ultrasound system. EA provides a tool for comparing the size of a lesion on the 2D image and on the elastogram and enables the user to determine the ratio of two regions of interest (ROI), referred to as Size Compare.

5) Intended Use

QLAB Quantification software is a software application package. It is designed to view and quantify image data acquired on Philips Medical Systems ultrasound products.

6) Technological comparison to predicate devices

Philips QLAB EA and the Size Compare feature on the Philips Ultrasound iU22 Ultrasound system are software tools for ultrasound image analysis. The Size Compare feature on the Ultrasound cart allows analysis during the Ultrasound exam while QLAB can be used as a standalone program for post-exam analysis and patient report preparation.

7) Non-clinical performance data

No performance standards for PACS systems or components have been issued under the authority of Section 514.

8) General Safety and Effectiveness Concerns

The device labeling contains operating instructions for the safe and effective use of the QLAB software.

9) Conclusions

The QLAB Quantification Software 8.1 is designed to incorporate components common to all image viewing systems for the display, manipulation and quantification tasks within a clinical setting. Software development for the QLAB software follows documented processes for software design, verification and validation testing. A risk assessment has been completed to identify potential design hazards that could cause an error or injury based on the use of the quantification results. Appropriate steps have been taken to control all identified risks for this type of image display and quantification product. The QLAB 8.1 software incorporates features of predicate devices cleared through premarket notification and no new issues of safety or effectiveness are raised.